

Cardinal Health 303, Inc. Signs Amended Consent Decree with FDA

22 Feb 2009

The U.S. Food and Drug Administration announced that California device manufacturer Cardinal Health 303 Inc., formerly known as Alaris Medical Systems Inc., and three of its top executives have signed an amended consent decree to correct violations of current Good Manufacturing Practice (cGMP) requirements in the company's infusion pumps.

Infusion pumps are devices intended for controlled delivery of intravenous solutions and medications to patients.

Under the terms of the amended consent decree, Cardinal 303 agrees to comply with the cGMP requirements and Quality System (QS) regulations in the designing, manufacturing, processing, packing, repacking, labeling, holding or distributing of its infusion pumps. Cardinal 303 also must retain an independent expert consultant to inspect all of its infusion pump facilities and recall procedures, and certify to the FDA that corrections have been made. Additionally, the company must submit to the FDA a detailed corrective action plan to bring all infusion pumps currently in use in the United States into compliance with the Federal Food, Drug, and Cosmetic Act (FDCA).

The decree covers all of the company's infusion pumps, including the Alaris System (formerly known as Medley) infusion pump, the Gemini infusion pump and the Med System III infusion pump.

In August 2006, U.S. Marshals seized certain models of Cardinal 303's Alaris SE (formerly known as the Signature Edition) line of infusion pumps at the company's manufacturing facility in San Diego, Calif. Subsequently, in 2007, Cardinal 303 signed a consent decree in which they agreed to cease manufacturing, processing or distributing the Alaris SE line of infusion pumps until the company corrected deviations from the QS regulations. Cardinal 303 is still in the process of making these corrections.

After the company signed the consent decree related to the SE line, FDA investigators found similar QS deviations relating to another line of Cardinal 303's infusion pumps. Among the deficiencies was a failure to notify the FDA in a timely manner after becoming aware that one of the company's infusion pumps had malfunctioned and that the device would be likely to cause or contribute to death or serious injury if the malfunction were to recur. Cardinal 303 also failed to establish and maintain procedures to review, evaluate, and investigate complaints of malfunction or failure of its pumps. Based on these violations, the FDA sought to amend the 2007 decree to cover all of Cardinal 303's infusion pumps.

Once Cardinal 303 makes the corrective actions specified in the decree, the company must hire an independent auditor to conduct annual audit inspections of all of its infusion pump facilities for at least four years and report the results to the FDA.

The amended consent decree also authorizes the FDA, in the event of future violations, to order Cardinal 303 to cease manufacturing and distributing, to recall products, and to take other actions. The defendants may be required to pay damages of \$15,000 per day if they fail to comply with any provisions of the decree, plus an additional \$15,000 for each violation, up to \$15 million per year.

The amended consent decree was filed on Feb. 18 in the U.S. District Court for the Southern District of California and is effective when entered by the court. The terms of the 2007 consent decree are still in effect.